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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

Pacira Pharmaceuticals, Inc., and Pacira BioSciences, Inc.,

Civil Action No. 2:21-cv-19829-MCA-CLW

Plaintiffs,

v.

eVenus Pharmaceuticals Laboratories Inc. and Jiangsu Hengrui Pharmaceuticals Co. Ltd., a Chinese Pharmaceutical Co.,

Defendants.

**PLAINTIFFS' ANSWER TO DEFENDANT'S COUNTERCLAIMS AND
AFFIRMATIVE DEFENSES**

Plaintiffs/Counterclaim-Defendants Pacira Pharmaceuticals, Inc., and Pacira BioSciences, Inc. (collectively “Pacira”) answer the numbered paragraphs of the Counterclaims of Defendant/Counterclaim-Plaintiff eVenus Pharmaceuticals Laboratories Inc. (“eVenus, “Defendant”), in Civil Action No. 2:21-cv-19829-MCA-CLW, as follows:

PARTIES

1. eVenus Pharmaceutical Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 506 Carnegie Center, Suite 100, Princeton, New Jersey, 08540.

ANSWER: On information and belief, admitted.

2. On information and belief, Pacira Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California, with its principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054. On information and belief, Pacira Pharmaceuticals, Inc. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, and distributing pharmaceutical drugs for the U.S. market.

ANSWER: Pacira Pharmaceuticals admits Pacira Pharmaceuticals is a corporation organized and existing under the laws of California, having a principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054. Pacira Pharmaceuticals admits that it is in the business of selling pharmaceutical products for markets including the United States. Otherwise denied.

3. On information and belief, Pacira BioSciences, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054. On information and belief, Pacira Biosciences, Inc. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, and distributing pharmaceutical drugs for the U.S. market.

ANSWER: Pacira BioSciences, Inc. admits Pacira BioSciences, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054. Pacira BioSciences, Inc. admits that it is in the business of selling pharmaceutical products for markets including the United States. Otherwise denied.

JURISDICTION AND VENUE

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, Pacira admits that the Defendants purport to bring a declaratory

judgment action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise denied.

5. The Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required and for the purposes of this case only, Pacira admits that the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Otherwise denied.

6. This Court has personal jurisdiction over Pacira because Pacira has availed itself of the rights and privileges, and has subjected itself to the jurisdiction, of this forum by suing eVenus and Jiangsu Hengrui and/or because Pacira conducts substantial business in, and has regular and systematic contacts with, this District.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Pacira admits that it commenced an action against Defendant in this District as set forth in the Complaint (EFC No. 1). Pacira does not contest personal jurisdiction in this Judicial District for the purposes of this case only. Otherwise denied.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Pacira admits that it commenced an action against Defendant in this District as set forth in the Complaint (EFC No. 1). Pacira does not contest venue in this Judicial District for the purposes of this case only. Otherwise denied.

FIRST CLAIM FOR RELIEF

(Declaratory Judgment of Noninfringement Of The '495 Patent)

8. Defendant reasserts and realleges Paragraphs 1-8 of Defendant's Counterclaims as if fully set forth herein.

ANSWER: Pacira hereby incorporates its responses to Paragraphs 1-7 of Defendant's Counterclaims as if fully set forth herein.

9. The manufacture, use, sale, offer for sale, and/or importation of bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL), that is the subject of eVenus's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '495 patent.

ANSWER: Denied.

10. There is an actual, substantial, and continuing justiciable case or controversy between Defendant and Pacira of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Defendant's non-infringement of the '495 patent.

ANSWER: This paragraph states legal conclusions to which no answer is required. To the extent that an answer is required, for the purpose of this case only, Pacira admits that there is an actual, substantial, and justiciable controversy between Pacira and Defendant regarding the infringement of the '495 patent. Otherwise denied.

11. Defendant is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL), that is the subject of eVenus's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '495 patent, either directly or indirectly.

ANSWER: Denied.

SECOND CLAIM FOR RELIEF

(Declaratory Judgment of Invalidity of the '495 Patent)

12. Defendant reasserts and realleges each of Paragraphs 1-12 of Defendant's Counterclaims as if fully set forth herein.

ANSWER: Pacira repeats and incorporates its responses to Paragraphs 1-11 of Defendant's Counterclaims.

13. The claims of the '495 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

ANSWER: Denied.

14. There is an actual, substantial, and continuing justiciable case or controversy between Defendant and Pacira of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '495 patent.

ANSWER: This paragraph states legal conclusions to which no answer is required. To the extent that an answer is required, Pacira admits that there is an actual, substantial, and continuing justiciable controversy between Pacira and Defendants regarding whether the claims of the '495 patent are valid. Otherwise denied.

15. Defendant is entitled to a judicial declaration that the claims of the '495 patent are invalid.

ANSWER: Denied.

DEFENDANT'S PRAYER FOR RELIEF

The "Prayer for Relief" paragraph concluding Defendant's counterclaims states Defendant's request for relief to which no answer is required. To the extent that an answer is required, Pacira denies the allegations set forth and denies that Defendant is entitled to the relief requested, or to any relief whatsoever.

AFFIRMATIVE DEFENSES

In response to Defendant's counterclaims, Plaintiffs assert the following affirmative and other defenses. In asserting these defenses, Plaintiffs do not assume the burden of proof with respect to any issue upon which applicable law places the burden of proof upon Defendant.

First Affirmative Defense

Defendant's counterclaims, in whole or in part, fail to state claims upon which relief can be granted.

Second Affirmative Defense

Defendant's counterclaims, in whole or in part, are non-justiciable.

Third Affirmative Defense

Plaintiffs have not knowingly or intentionally waived any applicable defenses and reserve the right to assert and rely upon such other affirmative defenses as may become available or

apparent during discovery proceedings. Plaintiffs further reserve the right to amend their Answer and/or Affirmative Defenses accordingly.

WHEREFORE, Plaintiffs respectfully request the following relief:

- (a) An order dismissing Defendant's Counterclaims with prejudice, and a judgment that Defendant is not entitled to the relief sought, or to any other relief on its Counterclaims;
- (b) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of eVenus's ANDA, or the commercial manufacture, use, or sale of the eVenus ANDA Product, or any other drug product that infringes or the use of which infringes the '495 patent, be not earlier than the expiration date of the '495 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, enjoining Defendants, and all persons acting in concert with Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the eVenus ANDA Product, or any other drug product covered by or whose use is covered by the '495 patent, prior to the expiration of the'495 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) An order granting each and every Request for Relief sought by Plaintiffs in their Complaint;
- (e) An award of Plaintiffs' costs and expenses in defending against Defendant's Counterclaims; and
- (f) such other and further relief as the Court deems just and proper.

Dated: January 27, 2022

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CERTIFICATE OF SERVICE

I hereby certify that on the date below, I caused a copy of the foregoing PLAINTIFFS' ANSWER TO DEFENDANT'S COUNTERCLAIMS AND AFFIRMATIVE DEFENSES to be filed on the Court's CM/ECF system, which will cause service on the attorneys of record for Defendants in this matter.

January 27, 2022

s/ Cynthia S. Betz

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